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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 24

Application Number: 09/025,279
Filing Date: February 18, 1998
Appellant(s): SHELTON, ROBERT H.

MAILED

JAN 28 2003

Technology Center 2100

Robert H. Shelton
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 10, 2001.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

No amendment after final has been filed.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that the claims stand and fall together.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

| | | |
|---|------------------|---------|
| 5,924,074 | Jae A. Evan | 07-1999 |
| A Security Policy Model for Clinical Information Systems | Ross J. Anderson | 02-1996 |

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims 1-81:

Claim Rejections - 35 U.S.C. § 103

I. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-43 and 45-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (U.S. Pat. No. 5,924,074).

As per claims 1 and 42, Evans teaches a medical data base supervisory control system as claimed comprises at least one database including medical data individually relating to each of a plurality of patients (thus, a medical records comprising a point of care system to capture patient data at a point of care and a patient data repository in communication with the point of care system and with external systems to store and organize the patient data for access by the point care system; which is readable as medical data individually relating to each of a plurality of patients) (see cols. 1-3, lines 65-3),

(b) means including interconnected computers for requesting and accessing said medical data (see figure 24, element 404),

(c) means for identifying medical data for each of said patients with condition required for accessing said medical data (thus, authorized health care providers can access a record while other providers use the same record, which is readable as identifying medical data for each of said patients with condition required for accessing said medical data) (see col. 2, lines 53-64).

But, Evans does not explicitly indicate data processing means responsive to a request for patient medical data for comparing said request with said conditions required for access to said data and, when said request fails to comply with said conditions, for denying access to said data.

However, Evans implicitly indicates the point of care system issues a request for patient data with reference to figure 15a, the patient locator receives the request from the point of care system and attempts to find the patient id for the record having the requested patient data as determined, if no patient id is found the patient locator reports an error at this point the patient data repository may recover from the error by either restarting the process or by ending the process; which is readable as data processing means responsive to a request for patient medical data for comparing said request with said conditions required for access to said data and, when said request fails to comply with said conditions, for denying access to said data) (see figure 15, col. 9, lines 39-48).

Further, in column 3, lines 9 through 24, Evans teaches wherein the patient record includes identifier and at least one data structure including the patient identifier and the data. Thus, it would have been obvious to a person of ordinary skill in the art to modify the teachings of Evans with the step of data processing means responsive to a request for patient medical data for comparing said request with said conditions required for access of said data and, when said request fails to comply with said conditions, for denying access to said data. This modification would allow the teachings of Evans to improve the accuracy and the reliability of the standing order database search system and method for internet and internet application, and provide instant access to a patient's electronic medical record by authorized health care providers from any geographical location (see col. 14, lines 65-67).

As per claims 2, 5, 43 and 46, Evans teaches a system as claimed further includes means for authenticating the identity of the requesting party (thus, the system provides several levels of security for access to patient data, which is readable as the identity of the requesting party) (see col. 15, lines 21-29).

As per claims 4 and 45, Evans teaches a method as claimed further includes step of tentatively identifying records fulfilling the criteria specified in said request for medical (thus, the health care provider can track referrals by entering the identity of persons who referred this patient to their care, which is readable as tentatively identifying records fulfilling the criteria specified in said request for medical) (see col. 6, lines 7-9).

As per claims 6-7, and 47-48, Evans teaches a system as claimed, wherein said means for requesting said medical data includes means for indicating what part of said records is desired (see figure 15A).

As per claims 8-9 and 49-50, Evans teaches a system as claimed, wherein said means for identifying records fulfilling such request further include data symbolic of medical symptoms or reason for patient visit (thus, the health care provider can track referrals by entering the identity of persons who referred this patient to their care, which is readable as wherein said means for identifying records fulfilling such request further include data symbolic of medical symptoms) (see figure 15A, elements 252, 254, cols. 6 and 9, lines 7-9, and 41-50).

As per claims 10-11 and 51-52, Evans teaches a system as claimed, wherein said means for identifying records fulfilling such request further include data symbolic of the attributes, levels or findings indicated within said diagnostic tests (thus, the system returns the provider to the patient chart window, which is readable as identifying records fulfilling) (see, figure 7, col. 7, lines 10-28).

As per claims 12-13 and 53-54, Evans teaches a system as claimed, wherein said means for identifying records fulfilling such request further include data symbolic of modes of

treatment or medical services rendered (thus, to consult regarding courses of action to obtain a diagnosis; which is readable as include data symbolic of modes of treatment or medical services rendered) (see, col. 7, lines 54-64).

As per claims 14-15 and 55-56, Evans teaches a system wherein said means used for identifying records fulfilling such request further include data symbolic of attending physician identity (thus, permits health care providers such as physicians to electronically annotate patient data, which is readable as identifying records fulfilling such request further include data symbolic of attending physician identity) (see col. 2, lines 50-54).

As per claims 16, 30 and 57, Evans teaches as claimed, wherein said means for requesting and accessing said medical data includes means for indicating a 'standing order' that will automatically initiate an attempt to retrieve certain pre-determined types of medical data under specific pre-specified circumstances (see col. 2, lines 21-31).

As per claims 17, 58 and 63, Evans teaches a system as claimed, wherein said conditions required for accessing said medical data includes an indication of the names of each of the parties who's permission must be obtained prior to the release of the such medical data (thus, wherein the patient record includes a patient identifier and at least one data structure including the patient identifier and the data, which is readable as for accessing said medical data includes an indication of the names of each of the parties who's permission must be obtained prior to the release of the such medical data) (see col. 3, lines 6-8).

As per claims 18-19, 59-61 and 78, Evans teaches a system as claimed, wherein said conditions required for accessing said medical data further includes an indication of the charge that will be assessed by the holder of such medical data for the part, or in the form, specified by the requesting party (see cols. 6 and 7, lines 54-67 and 1-5).

As per claims 20, 22, 34 and 75, Evans teaches a system as claimed, wherein said at least one data base includes a firewall limiting access to searching such data base solely to those

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parties who are authorized to do so (thus, system administrator may have global password access, which is readable as said at least one data base includes a firewall limiting access to searching) (see col. 15, lines 24-29).

As per claims 21, 31, 62 and 72, Evans teaches a system as claimed, wherein said means for identifying medical data fulfilling the criteria specified in a request include a means for producing an indicia of the degree to which data listed in such data index match the criteria specified in such request (thus, group data associated with a patient within the data archive for rapid retrieval in a manner similar to files within a directory in an operating system, which is readable as identifying medical data fulfilling the criteria specified in a request include a means for producing an indicia of the degree to which data listed in such data index match the criteria specified in such request) (see col. 9, lines 28-37).

As per claims 23 and 67, Evans teaches a system as claimed, wherein said at least one data base includes a billing means for access to said medical data (thus these files may also include the patient's billing payment and scheduling records, which is readable as wherein said at least one data base includes a billing means for access to said medical data) (see col. 1, lines 25-30).

As per claims 24-25, 64 and 66, Evans teaches a system as claimed, wherein said means to grant permission includes data symbolic of the identity of such party and data symbolic of the preferred means for contacting such party to request access to and release of said patient's medical data (see col. 3, lines 24-30).

As per claims 26, 43 and 45-46, Evans teaches a system as claimed, further includes means for identifying the party requesting access to such medical data (see figures 17A and 17B, col. 10, lines 42).

As per claims 27-29, 68-69 and 73, Evans teaches a method as claimed, further includes means for producing an indicia of the required approvals for the release of such medical data that have not been secured, or that have been specifically declined (see col. 2, lines 53-60).

As per claims 32-33 and 40, Evans teaches a system as claimed, further includes means for billing said requesting party for the charge related to access to the medical data (thus these files may also include the patient's billing payment and scheduling which is readable as records means for billing said requesting party for the charge related to access to the medical data) (see col. 1, lines 25-30).

As per claims 35-36 and 71, Evans teaches a system as claimed, further includes means for producing an indicia that the requested medical data have been received in an online memory cache means and are being held there for download by the requesting party (see cols. 9 and 10, lines 61-67, and 1-17).

As per claims 37, 39, 47 and 80-81, Evans teaches a method as claimed, further includes the step of creating a security log and retaining an audit trail with regard to all of the communications between the parties (see col. 3, lines 25-30).

As per claims 38, 74 and 79, Evans teaches a system as claimed, further includes means for informing the requesting party when medical data is in a non-digital form and the mode of such delivery (see col. 1, lines 53-64).

As per claim 41, Evans discloses a system as claimed, further comprises means for allowing parties to advertise in the public portions of said system (see figure 22).

As per claim 65 and 70, Evan teaches a method as claimed, wherein said step of providing for a party to grant permission includes data symbolic of the identity of such party and data symbolic of the preferred means for contacting such party to request access to and to the release of said patient's medical data (see col. 2, lines 53-60).

As per claims 76 and 77, Evans teaches a method as claimed, further includes step of permitting a properly credentialed requesting party to enter through the firewall and download said medical data from the memory cache (thus, if the data in the cache is not ready for transfer the process ends and the data manager queues the request for the next transfer of data to the data archive, which is readable as permitting a properly credentialed requesting party to enter through the firewall and download said medical data from the memory cache) (see col. 10, lines 10-17).

II. Claims 3 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (U.S. Pat. No. 5,924,074) in view of Anderson, R. J. (A Security Policy Model for Clinical Information System; 6-8 May, 1996) ("Evans"), ("Anderson").

As per claims 3 and 44, Evans teaches the claimed subject matter except the claimed including means to prevent access to formation concerning medical records by any party without the prior authorization of the patient about whom such records pertain. However, Anderson teaches patient's consent must be sought for other person such as the clinician's colleagues to be added to the access control list and must be notified of every addition, (see page 35, cols. 1 and 2, lines 46-9 and 1-4). Further, in page 31, column 1, lines 42 through 44, Anderson teaches if researchers want access to records which cannot effectively be made anonymous, then every effort must be made to inform the patient and gain his consent. Thus, it would have been obvious to a person of ordinary skill in the art to modify the teachings of Evans and Anderson with steps to prevent access to formation concerning medical records by any party without the prior authorization of the patient about whom such records pertain. This modification would allow the teachings of Evans and Anderson to improve the accuracy and the reliability of the standing order database search system and method for internet and internet application, and

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provide ensure that any lack of consent is propagated and enforced (see page 41, col. 2, lines 49-50).

(11) Response to Arguments

The Examiner will address the issues raised by the appellant in the order in which they appear in the appeal brief.

Appellant's to response, page 16 of the brief asserted that, "Appellant has been unable to find any teaching or suggestion of the conditions required for access to patient data coupled with the overt denial of access as claimed by the claims on appeal." This assertion is incorrect because Evans indicates the point of care system issues a request for patient data, the patient locator receives the request from the point of care system and attempt to find the patient ID for the record having the requested patient data, as determined if no patient ID is found the patient locator reports an error, at this point the patient data repository may recover from the error by either restarting the process or by ending the process ("ending process" is readable as denied access), (see col. 9, lines 39-48). Thus, it would have been obvious to a person of ordinary skill in the art to modify the teachings of Evans with conditions required for access to patient data coupled with the overt denial of access. This modification would allow the teachings of Evans and Anderson to provide access to reference databases for diagnosis (see col. 2, lines 63-64).

In response to Appellant's argument on page 17 of the brief, that claim be interpreted in light of the specification, it should be noted that during patent examination, the pending claims must be 'given the broadest reasonable interpretation consistent with the specification.'

Applicant always has the opportunity to amend the claims during prosecution and broad

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interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. In re Prater, 162 USPQ 541,550-51 (CCPA 1969). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Genus, 988 F.d. 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to Appellant's argument, page 19 of the brief, that "the patient identifier appears merely to be a convenient tool to assist in locating a patient record and is irrelevant to the question of conditions required to avoid denial of access." Implicitly Evans indicates as determined if no patient ID is found the patient locator reports an error at this point the patient data repository may recover from the error by either restarting the process or by ending the process ("ending process" is readable as denied access), (see col. 9, lines 39-48). Therefore, those who cannot be accessed the system have been denied. Thus, the arguments are not persuasive.

On page 21 of the brief, Appellant stated that "Applicant's system that is intended to protect the integrity of the information even in the instance that such identifier was accurately entered. The fact that the system in Evans was unable to process for a record whose identifier was entered in error is far from being a privacy mechanism. Clearly, Evans had no such intention." However, Examiner disagrees because Evans includes the patient locator 200 generates a unique patient identifier 221 for each patient and create and maintains a table having patient identifiers for all patients who have data in the patient data repository 102, (see col. 8, lines 22-28). Although Evans does not explicitly indicate the steps of claims 1 and 42, Evans clearly teaches the claimed system.

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On page 24 of the brief, Appellant stated that "Evan's system would fail to provide any protection for the data in the memory cache in such instance, whereas the data in Appellant's system would be secure." However, Examiner disagrees because Evans includes the patient data repository 102 may optionally include a cache 206 for temporary storage of patient data and a data archive 208 for long term storage of patient data, the data manager 202 coordinates the transfer of patient data to and from a data archive 208 into a cache 206, the data manager 202 will group data associated with a patient within the data archive 208 for rapid retrieval in a manner similar to files within a directory in an operating system, thus the data manager 202 assigns a directory to each patient identifier and then stores patient data within this directory, (see col. 9, lines 15-37).

In response to Appellant's argument, pages 34 and 42 of the brief, that the Examiner has ignored the mandate of the modern case law from the Court of Appeals for the Federal Circuit which clearly and explicitly hold that in order for the references to be combined in that the references must explicitly teach or suggest the combination as well as the potential benefit which may be derived from such a combination, the Examiner respectfully submits that Applicant misinterprets the case law which he cites. For example, the Court in In re Fritch stated "[The Examiner] can satisfy this burden only by showing some objective teaching in the prior art *or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.* [emphasis added]" In re Fine, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing In re Lalu, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). Each applied reference does not expressly suggest combination with the other respective references; however, the Examiner has shown that

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motivation for combining the references existed in the prior art. The "modification" referred to in In re Fritch involves extensive changes to the primary references. Such is not the case in the present combinations, where all modifications proposed by the Examiner are taught by the references. Therefore, the combination of references is proper.

In response to Appellant's argument, pages 34-36 of the brief, that "the Anderson reference is not properly combinable with Evans without the use of impermissible hindsight," the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Anderson teaches researchers want access to records which cannot effectively be made anonymous then every effort must be made to inform the patient and gain his consent, (see Anderson page 31, col. 1, lines 39-44).

In response to Appellant's argument, page 39 of the brief, that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Do not share) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument, pages 40-41 of the brief, that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight

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reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

As per Appellant's argument, page 44 of the brief, that "it must indicate where teaching or suggestion appears in the references," Appellant appears to misinterpret the guidance given under MPEP 2142. In particular, references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969).


For the above reasons, it is believed that the rejections of claims 1-81 should be sustained.



Jean Bolte Fleurantin

Respectfully submitted,

Examiner AU 2172

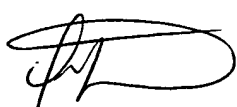
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